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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,659	02/20/2004	Kyogo Itoh	0020-5224P	5788

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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/19/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/781,659	ITOH ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8,11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09763985.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/05, 2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *exhibit A*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II (claims 2-15) with SEQ ID NO: 3 and species phenylalanine at position 2 and isoleucine for C-terminus in the reply filed on 10/19/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-15 are pending. Claims 1, 9, and 10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species. After review and reconsideration of the elected species in light of the art, the species tyrosine in position 2 and leucine in the C-terminus are joined to the species phenylalanine and isoleucine for examination at this time. Thus, claims 2-8 and 11-15 to the extent of SEQ ID NO: 3 and amino acid substitution of phenylalanine and tyrosine at position 2 and isoleucine and leucine for C-terminus are examined on the merits.

Priority

This application claims benefit of foreign applications, Japan 242660/1998 filed 8/28/1998 and Japan PCT/JP99/04622 filed 8/27/1999 is acknowledged.

Upon review of documents submitted to the Office, it is noted that no English translation for both applications were submitted with this application. Since intervening reference is applied below, the claims are currently given a priority date of 8/27/1999.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 2/20/04 and 1/4/05 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Specification

Amendment to the specification by adding SEQ ID NOs and deleting the hyper-linkers filed on 2/20/04 is acknowledged and entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-8 and 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claimed product, tumor antigen peptide, is a partial peptide of a natural existed protein (SEQ ID NO: 2) and comprises the peptide of SEQ ID NO:3. The peptide exists in nature, which does not constitute patentable subject matter as defined in 35 U.S.C. 101. The claimed inventions do not show involvement of the "hand of man". Amending the claims to require that the tumor antigen peptides are purified or isolated would indicate the "hand of Man".

Claim Rejections - 35 USC § 112

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is further drawn to one of claims 2-10 and recites " at least one of DNAs that encode.....according to any one of claims 2 to 10" in the claim. There is insufficient antecedent basis for this limitation in the claim because none of claims 2-10 recites DNA. Claim 12 renders its dependent claims 13 and 15 indefinite.

The following is a quotation of the **first paragraph of 35 U.S.C. 112:**

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Drawn to Written Description:

Claims 2-8 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Claims are broadly drawn to tumor antigen peptide that is a partial peptide of SEQ ID NO: 2 comprising an amino cid sequence shown by SEQ ID NO: 3 (10 amino acids at position 109-118 of SEQ ID NO: 2), or derivatives of tumor antigen peptides having amino acid substitution at position 2 and/or the C-terminus in the peptide of SEQ ID NO: 3, which bind to an HLA antigen and is recognized by cytotoxic T-lymphocytes. Thus, the claims are inclusive of a genus of tumor antigen peptides that can be any fragment of SEQ ID NO: 2 comprising an amino acid sequence of SEQ ID NO: 3 and derivative thereof with amino acid substitutions of SEQ ID NO: 3. The claimed reciting an amino acid sequence of SEQ ID NO: 3 could be as small as only two amino acid peptide (claims 4-5). The specification also asserts that the amino acid in the SEQ ID NO: 3 can be substituted at position 2 and C-terminus. Thus, the claims encompass a significant structural and functional dissimilarity and diversity as compared to this peptide consisting of SEQ ID NO: 3. The specification as filed does not provide adequate written description support for the claimed tumor antigen peptide that are partial peptide of SEQ ID NO: 2 comprising an amino acid sequence of SEQ ID NO: 3 or its derivative.

The specification on page 22 discloses a method for identifying tumor antigen peptide and states that if the candidate induces CTL that specifically recognized the HLA-antigen-presenting cells.....indicated that the particular candidate peptide may function as tumor antigen peptide. However, the specification, page 62-64, example 6, only reasonably conveys that the peptides of SEQ ID NO: 3 and 6 (non-elected invention), which are fragments of SEQ ID NO: 2 at positions 109-118 and 315-323 bind to HLA-A24 antigen and be recognized by cytotoxic T-lymphocytes, no derivatives of SEQ ID NO: 3 having such tumor antigen function as the peptide of SEQ ID NO: 3 were described.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d

1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristic, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613".

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d ,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The mechanism of binding peptide to HLA and being recognized by T-lymphocyte is well known by one skilled in the art. Every peptide against which an immune response can be generated must contain some residues that contribute to biding to the clefts of MHC (HLA-2) and must also contain other residues that project from the clefts, where they are recognized by T-cells. The peptide that binds to HLA molecules shares structural feature that promote this interaction (see Abbas et al., Cellular and Molecular Immunology, 4th edition. 2000, page71-72). The instant specification fails to provide sufficient descriptive information, such as definitive or shared structural or functional features that are common to the claimed tumor antigen peptide for binding of HLA and being recognized by T-lymphocytes. That is, the specification provides neither a representative number of tumor peptide antigens of derivative of SEQ ID NO: 3 or partial peptide of SEQ ID NO: 2 that encompass the genus that reveal the roles of tumor antigen nor does it provide a description of structural features that are common to the peptide of SEQ ID NO: 3 is associated with HLA-A24 binding and being recognized by cytotoxic T-lymphocytes. Described peptide of SEQ ID NO: 6 does not share a common structure or sequence with SEQ ID NO: 3. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and

because the genus is highly variant, the disclosure of amino acid sequence of SE ID NO: 3 is insufficient to describe the genus of partial peptide of SEQ ID NO: 2. Thus, one of skill in the art would reasonably conclude that the inventor(s), at the time the application was filed, did not have possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) and functional attribute(s) of the encompassed genus of tumor antigen peptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only tumor antigen peptide consisting of amino acid sequence of SEQ ID NO: 3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112 paragraph 1" Written Description" Requirement. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as filed.

Drawn to scope of enablement

Claims 2-8 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tumor antigen peptide consisting of the amino acid SEQ ID NO: 3 does not reasonably provide for the other partial peptide of a protein having a SEQ ID NO: 2 or derivative thereof of the SEQ ID NO: 3 is most nearly connected, to use the invention commensurate in scope with these claims.

The factor considered when determining if the disclosure satisfies the enablement requirement and whether any is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of necessary experimentation claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands,* 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir.1988).

The claims are broadly drawn to a tumor antigen peptide is a partial peptide of SEQ ID NO: 2 comprising a peptide having an amino acid sequence (could be as small as only two amino acid peptide) of SEQ ID NO: 3 or derivative thereof that binds to and is recognized by HLA-A24 restricted T-lymphocytes. To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. Thus, it would be expected that one of skill in the art would be able to make and use the claimed peptide as a tumor antigen, which is recognized and activated by T-lymphocytes.

The specification on page 22 discloses a method for identifying tumor antigen peptide and states that if the candidate induces CTL that specifically recognized the HLA-antigen-presenting cells.....indicated that the particular candidate peptide may function as tumor antigen peptide. However, the specification, page 62-64, example 6, only reasonably conveys one peptide of SEQ ID NO: 3 having tumor antigen activity and is recognized by HLA-A24-restricted T-cells, no derivatives of SEQ ID NO: 3 or other claimed partial peptide of SEQ ID NO: 2 comprising SEQ ID NO: 3 could bind to HLA-A24 and are recognized by T-lymphocytes. Again as discussed above, every peptide against which an immune response can be generated must contain some residues that contribute to binding to the clefts of MHC

(HLA-2) and must also contain other residues that project from the clefts, where they are recognized by T-cells. The peptide that binds to HLA molecules shares structural feature that promote this interaction (see Abbas et al., Cellular and Molecular Immunology, 4th edition. 2000, page71-72). The specification does not provide such common structure in the peptide of SEQ ID NO: 3 that enable the claimed peptide for the binding of HLA-A24 and being recognized by T-cells. In the absence of this minimally shared structure, applicant would have to screen a large amount of peptide fragment of SEQ ID NO: 2 to determine whether a peptide can be a tumor antigen based on the ability of binding to HLA-A24 and being recognized by T-lymphocyte. Yang et al., (Cancer Res, 59:4056-4063, Aug, 15,1999) teach a protein SART3 that have the amino acid sequence of SEQ ID NO: 2. Yang et al., teach that peptides, SART3 $_{109-118}$ and SART3 $_{315-323}$ as partial peptides of SEQ ID NO: 2 at position 109-118 (identical to SEQ ID NO: 3) and position 315-323 having an ability to bind to HLA-A24 and be recognized by T-lymphocyte. Yang et al., teach that the rest peptide fragments of the SART3 protein have much less or no binding to HLA-A24 and not being recognized or activated by T cells. Thus, the reference by Yang et al., clearly teach that NOT every partial peptide of the protein (SEQ ID NO: 2) has an ability to bind to an HLA-A24 and be recognized by cytotoxic T-lymphocytes.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to the structure to bind to HLA-A24 and be recognized by cytotoxic T-lymphocytes, one skilled in the art would be forced into under experimentation in order to practice the broadly claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims are drawn to a tumor antigen peptide that is partial peptide of a protein having amino acid sequence of SEQ ID NO: 2 or the peptide comprising an amino acid sequence of SEQ ID NO:3 or derivative thereof with substitution at position 2 and/or C-terminus that bind to HLA-A24 and are recognized by cytotoxic T-lymphocytes and compositions or diagnostic agents comprise such. For this rejection the intended use of a pharmaceutical composition and diagnostic agent is given no patentable weight.

1. Claims 2-8 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated Uniprot-7.2 database Accession No, Q15020 and Nagase et al., (DNA Res, 2:167-174, 1995) as evidenced by sequence search and alignment.

Uniprot database, Q15020, and Nagase et al., (KIAA0156 in table 1) disclose a protein comprising SEQ ID NO: 3 as evidenced by attached sequence alignment (exhibit A). Since the protein disclosed in Unipro database and Nagase et al., is identical to the claimed peptide, it is inherent that the protein would bind to HLA antigen and be recognized by cytotoxic T-lymphocytes.

3. Claims 2-8 and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang et al., (Cancer Res, 59:4056-4063, Aug, 15,1999) as evidenced by protein sequence search Uniprot-7.2 database Accession No, Q15020 (exhibit A).

Yang et al., et al., disclose a peptide (SART3 109-118) that is identical to the amino acid sequence of SEQ ID NO: 3, which is a partial peptide of SEQ ID NO: 2 of claim 1 (figure 6b, line 1, page 4060). Yang et al., et al., also disclose that the peptide binds to HLA-A24 and is recognized by cytotoxic T-lymphocytes (page 4060, fig 6 and table 2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Copending application 10505955:

Claims 2-5 and 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 and 43 of copending Application No. 10505955 ('955). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 2-5 and 12 are drawn to a tumor antigen peptide that is partial peptide of a protein having amino acid sequence of SEQ ID NO: 2 or the peptide comprising an amino acid sequence of SEQ ID NO: 3. Claims 11-15 are drawn to a pharmaceutical composition and diagnostic agent having active component of SEQ ID NO: 3 or a partial peptide of SEQ ID NO: 2.

Claim 35 and 43 of copending application 10505955 ('955) teaches pharmaceutical composition having an antigen peptide represented by SEQ ID NOs:1-30. The amino acid sequence of SEQ ID NO: 21 in the copending application '955 is identical to instant claimed peptide (SEQ ID NO: 3) and is a partial peptide of SEQ ID NO: 2.

Claims 35 and 43 of the copending application '955 do not teach that the peptide binds to HLA-A24 and is recognized by cytotoxic T-lymphocytes. However, both sets of claim are directed to tumor antigen peptide or the peptide containing pharmaceutical composition. The difference between the two sets of claims is that the claims of copending application do not encompasses intended use to bind to HLA-A24 and be recognized by T-lymphocytes and the peptide is only presented in the pharmaceutical composition, which would not be given any patentable weight. Thus the only difference between the two sets of claims is intent use of the peptide. Because both set of the claims encompass an identical peptide alone or in the pharmaceutical composition the claim(s) are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Copending application 10788016:

Claims 2-5 and 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 19 and 23 of copending Application No. 10788016 ('016). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 2-5 and 12 are drawn to a tumor antigen peptide that is partial peptide of a protein having amino acid sequence of SEQ ID NO: 2 or the peptide comprising an amino acid sequence of SEQ ID NO: 3 or thereof, wherein the peptide binds to HLA antigen and is recognized by cytotoxic T lymphocytes. Claims 11-15 are drawn to a pharmaceutical composition and diagnostic agent having active component of SEQ ID NO: 3 or partial peptide of SEQ ID NO: 2.

Claims 11, 19 and 23 of copending Application '016 teach an agent comprising a peptide of SEQ ID NO: 7 to suppress allergic reaction (claim 11) or a vaccine comprising a peptide of SEQ ID NO:7 to be used to induce cytotoxic T-lymphocyte reaction (claims 19 and 23). The SEQ ID NO: 7 in the copending application '016, is identical to instant claimed peptide of SEQ ID NO: 3. The composition or vaccine in claims 11 and 23 further comprise a peptide of SEQ ID NO: 8.

Instant claims does not teach intended use of the peptide for suppress immune response and the composition does not include an additional peptide of SEQ ID NO: 8. However, both sets of claims are directed to antigen peptide. The difference between the two sets of claims is: A) that the claim 11 of copending application '016 do not encompasses intended use to bind to HLA-A24, instead intended use of the peptide to suppress allergic reaction. Since the peptides in both applications are identical, it is inherent that the peptides have same function. In addition, intended use is not given patentable weight. B) The claims in application '016 further comprise a peptide of SEQ ID NO: 8, thus, the difference between the two sets of claims are the scope of the claims. Because both set of the claims encompass an identical peptide the claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

<!--StartFragment-->GenCore version 5.1.9

OM protein - protein search, using sw model

Run on: December 4, 2006, 19:15:34 ; Search time 141 Seconds
(without alignments)
65.604 Million cell updates/sec

Title: US-10-781-659-3
Perfect score: 61
Sequence: 1 VYDYNCHVDL 10

Exhibit B

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 2849598 seqs, 925015592 residues

Total number of hits satisfying chosen parameters: 2849598

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : UniProt_7.2:*
1: uniprot_sprot:*
2: uniprot_trembl:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

<!--EndFragment-->

<!--StartFragment--> ALIGNMENTS

```
RESULT 1
SART3_HUMAN
ID   SART3_HUMAN    STANDARD;      PRT;   963 AA.
AC   Q15020; Q58F06; Q8IUS1; Q96J95;
DT   07-FEB-2006, integrated into UniProtKB/Swiss-Prot.
DT   01-NOV-1996, sequence version 1.
DT   21-FEB-2006, entry version 35.
DE   Squamous cell carcinoma antigen recognized by T cells 3 (SART-3)
DE   (hSART-3) (Tat-interacting protein of 110 kDa) (Tip110).
GN   Name=SART3; Synonyms=KIAA0156, TIP110;
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini; Hominidae;
OC   Homo.
OX   NCBI_TaxID=9606;
RN   [1]
RP   NUCLEOTIDE SEQUENCE [MRNA] (ISOFORM 1), AND SUBCELLULAR LOCATION.
RX   PubMed=10463607;
RA   Yang D., Nakao M., Shichijo S., Sasatomi T., Takasu H., Matsumoto H.,
RA   Mori K., Hayashi A., Yamana H., Shirouzu K., Itoh K.;
RT   "Identification of a gene coding for a protein possessing shared tumor
RT   epitopes capable of inducing HLA-A24-restricted cytotoxic T
RT   lymphocytes in cancer patients.";
RL   Cancer Res. 59:4056-4063(1999).
RN   [2]
RP   NUCLEOTIDE SEQUENCE [MRNA] (ISOFORM 2), TISSUE SPECIFICITY,
RP   SUBCELLULAR LOCATION, FUNCTION, AND INTERACTION WITH TAT.
RC   TISSUE=Fetal brain;
RX   MEDLINE=22075130; PubMed=11959860; DOI=10.1074/jbc.M200773200;
RA   Liu Y., Li J., Kim B.O., Pace B.S., He J.J.;
RT   "HIV-1 Tat protein-mediated transactivation of the HIV-1 long terminal
RT   repeat promoter is potentiated by a novel nuclear Tat-interacting
RT   protein of 110 kDa, Tip110.";
RL   J. Biol. Chem. 277:23854-23863(2002).
RN   [3]
RP   NUCLEOTIDE SEQUENCE [LARGE SCALE MRNA] (ISOFORM 1).
RC   TISSUE=Bone marrow;
RX   MEDLINE=96127530; PubMed=8590280; DOI=10.1093/dnares/2.4.167;
RA   Nagase T., Seki N., Tanaka A., Ishikawa K., Nomura N.;
RT   "Prediction of the coding sequences of unidentified human genes. IV.
RT   The coding sequences of 40 new genes (KIAA0121-KIAA0160) deduced by
RT   analysis of cDNA clones from human cell line KG-1.";
RL   DNA Res. 2:167-174(1995).
RN   [4]
RP   NUCLEOTIDE SEQUENCE [LARGE SCALE MRNA] (ISOFORMS 1 AND 3).
RC   TISSUE=Brain, Eye, Skin, and Uterus;
RX   MEDLINE=22388257; PubMed=12477932; DOI=10.1073/pnas.242603899;
RA   Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G.,
RA   Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D.,
RA   Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K.,
RA   Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F.,
RA   Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L.,
RA   Stapleton M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E.,
RA   Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C.,
RA   Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullahy S.J.,
RA   Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H.,
RA   Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W.,
RA   Villalon D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A.,
RA   Fahey J., Helton E., Ketteman M., Madan A., Rodrigues S., Sanchez A.,
RA   Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G.,
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RA   Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C.,
RA   Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M.,
RA   Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E.,
RA   Schnerch A., Schein J.E., Jones S.J.M., Marra M.A.;
RT   "Generation and initial analysis of more than 15,000 full-length human
RT   and mouse cDNA sequences.";
RL   Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).
CC   -!- FUNCTION: Regulates Tat transactivation activity through direct
CC       interaction. May be a cellular factor for HIV-1 gene expression
CC       and viral replication.
CC   -!- SUBUNIT: Interacts with HIV-1 Tat.
CC   -!- SUBCELLULAR LOCATION: Cytoplasm. Nuclear; localized in speckles.
CC       Expressed in the nucleus of all of the malignant tumor cell lines
CC       tested and the majority of cancer tissues with various
CC       histologies, including squamous cell carcinomas (SCC),
CC       adenocarcinomas, melanomas and leukemias cells. However, this
CC       protein is undectable in the nucleus of any cell lines of
CC       nonmalignant cells or normal tissues, except for the testis.
CC       Expressed in the cytoplasm of all the proliferating cells,
CC       including normal and malignant cells, but not in normal tissues,
CC       except for the testis and the fetal liver.
CC   -!- ALTERNATIVE PRODUCTS:
CC       Event=Alternative splicing; Named isoforms=3;
CC       Name=1;
CC         IsoId=Q15020-1; Sequence=Displayed;
CC       Name=2;
CC         IsoId=Q15020-2; Sequence=VSP_017250, VSP_017251;
CC         Note=No experimental confirmation available;
CC       Name=3;
CC         IsoId=Q15020-3; Sequence=VSP_017248, VSP_017249;
CC         Note=No experimental confirmation available;
CC   -!- TISSUE SPECIFICITY: Ubiquitously expressed.
CC   -!- SIMILARITY: Contains 8 HAT repeats.
CC   -!- SIMILARITY: Contains 2 RRM (RNA recognition motif) domains.
CC   ---------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ---------------------------------------------------------------------
DR   EMBL; AF387506; AAK69347.1; -; mRNA.
DR   EMBL; AB020880; BAA78384.1; -; mRNA.
DR   EMBL; D63879; BAA09929.1; -; mRNA.
DR   EMBL; BC032601; AAH32601.1; -; mRNA.
DR   EMBL; BC041638; AAH41638.1; -; mRNA.
DR   EMBL; BC093784; AAH93784.1; -; mRNA.
DR   EMBL; BC103706; AAI03707.1; -; mRNA.
DR   HSSP; Q14103; 1IQT.
DR   Ensembl; ENSG00000075856; Homo sapiens.
DR   HGNC; HGNC:16860; SART3.
DR   InterPro; IPR012677; a_b_plait_nuc_bd.
DR   InterPro; IPR003107; HAT.
DR   InterPro; IPR008669; Lsm_interact.
DR   InterPro; IPR000504; RNP1_RNA_bd.
DR   Pfam; PF05391; Lsm_interact; 1.
DR   Pfam; PF00076; RRM_1; 2.
DR   SMART; SM00360; RRM; 2.
DR   PROSITE; PS50102; RRM; 2.
KW   Alternative splicing; Antigen; Coiled coil; Nuclear protein; Repeat;
KW   RNA-binding.
FT   CHAIN         1    963       Squamous cell carcinoma antigen
FT                                recognized by T cells 3.
FT                                /FTId=PRO_0000223313.
FT   REPEAT      126    158       HAT 1.
FT   REPEAT      164    195       HAT 2.
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FT   REPEAT      201    237       HAT 3.
FT   REPEAT      242    275       HAT 4.
FT   REPEAT      324    356       HAT 5.
FT   REPEAT      359    391       HAT 6.
FT   REPEAT      394    430       HAT 7.
FT   REPEAT      487    520       HAT 8.
FT   DOMAIN      704    782       RRM 1.
FT   DOMAIN      801    878       RRM 2.
FT   REGION      600    670       Required for nuclear localization.
FT   COILED       21     46       Potential.
FT   COILED       82    110       Potential.
FT   COILED      559    619       Potential.
FT   MOTIF       601    617       Nuclear localization signal (Potential).
FT   COMPBIAS     89     92       Poly-Glu.
FT   COMPBIAS    612    616       Poly-Lys.
FT   VARSPLIC    105    129       LSINVYDYNCHVDLIRLLRLEGELT -> VGPGVGSGHLPV
FT                                FQVLGSPCPGPPP (in isoform 3).
FT                                /FTId=VSP_017248.
FT   VARSPLIC    130    963       Missing (in isoform 3).
FT                                /FTId=VSP_017249.
FT   VARSPLIC    351    364       SQYLDRQLKVKDLV -> RSTTESKGFGFICT (in
FT                                isoform 2).
FT                                /FTId=VSP_017250.
FT   VARSPLIC    365    963       Missing (in isoform 2).
FT                                /FTId=VSP_017251.
SQ   SEQUENCE   963 AA;  109935 MW;  06B26CEB8B19102A CRC64;

  Query Match             100.0%;  Score 61;  DB 1;  Length 963;
  Best Local Similarity   100.0%;  Pred. No. 0.14;
  Matches   10;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 VYDYNCHVDL 10
              ||||||||||
Db        109 VYDYNCHVDL 118

<!--EndFragment-->
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